K113034

DEC 1 3 2011

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	October 5, 2011
Submitter:	GE Healthcare GE Medical Systems, SCS 283 rue de la Miniere Buc, FRANCE, 78530 T: +33-01-30-70-42-07
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Secondary Contact Person:	Carol Alloian Regulatory Affairs Leader, GE Healthcare- Americas 9900 W innovation drive Wauwatosa, WI, USA, 53226-4856 T: (847) 244-8327 F: (847) 589-8524 Email: carol.alloian@ge.com
Device/Trade Name:	Innova Systems (Innova 4100-IQ, 3100-IQ, 2100-IQ)
Common/Usual Name:	Innova Systems (Innova 4100-IQ, 3100-IQ, 2100-IQ)
Classification Names: Product Code:	Angiographic x-ray system IZI, 892.1600.
Predicate Device(s):	K111209: INTEGRATED INNOVA - S5I SYSTEM OPTION, K090745 : Siemens Artis zee
Device Description:	The basis for this submission is a modification of the common platform of a family of legally marketed devices to expand its indications for use to include image-guided surgical procedures and open surgery procedures. The currently cleared devices are indicated for use for interventional and minimally invasive procedures. The subject modification is intended to introduce a new configuration (OR configuration) that will enable the Innova Systems

	to be additionally indicated for use in generating fluoroscopic and rotational images of human anatomy for image-guided surgical procedures. The modifications mainly consist of introduction of new configuration called OR configuration. The OR configuration of the product is designed in accordance with the operating table standard (IEC 60601-2-46) with deviation for clause 36.101*, it corresponds to the Innova 4100-IQ, 3100-IQ, 2100-IQ product equipped with • OR table (OR table is the Innova-IQ table with specific covers with an "OR" branding) • IPX4Table side user interface • Mandatory UPS • Mandatory surgical accessories • Dedicated surgery protocols *Electromagnetic Compatibility tested to cover high power surgical tool up to 300W and as per the Requirements of the IEC 60601-2-46 Edition 2, refer details in section 9.3.1 standards data forms 3654. To maintain compliance with the operating table safety standard, not all controls are allowed to be mounted on the table rails. The following controls only are allowed: • IPX4 Table Side Status Control (TSSC) • IPX4 Smart Box (Smart Box) • IPX4 Table Panning Device (TPD) • IPX4 Innova Central touch screen • IVUS PIM A table side cart is provided to place any other control (3D mouse, IVUS console and joystick) Table mounted injectors are not allowed with the OR configuration.
Intended Use:	The angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures. Additionally, with the OR table, the angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for image-guided surgical procedures. The OR table is suitable for interventional and surgical procedures.
Technology:	The Innova Systems employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The Innova Systems –OR configuration complies with voluntary standards as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the system: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Performance testing (Verification) • Safety testing (Verification) • Simulated use testing (Validation) Summary of Clinical Tests: The subject of this premarket submission, Innova Systems -OR configuration, did not require clinical studies to support substantial equivalence.
Conclusion:	GE Healthcare considers the Innova Systems –OR configuration to be as safe, as effective as its predicates devices, and its performances substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Re: K113034
Trade/Device Name: Innova Systems- OR configuration (Innova 4100-IQ, 3100-IQ, 2100-IQ)
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: October 5, 2011
Received: October 11, 2011

Dear Ms. Alloian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Innova Systems- OR configuration (Innova 4100-IQ, 3100-IQ, 2100-IQ)

Indications for Use

The angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures. Additionally, with the OR table, the angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for image-guided surgical procedures. The OR table is suitable for interventional and surgical procedures.

Prescription Use_X__ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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Prescription Use (Per 21 CFR 801.109)